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October 9, 2019

VIA ECF AND OVERNIGHT MAIL

Honorable Freda L. Wolfson, Chief Judge
United States District Court - District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street, Court Room 5E
Trenton, NJ 08608

Re: In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation, MDL No. 2728

Dear Judge Wolfson:

Defendants are cognizant of the Court's admonition that it would not accept additional briefing related to the *Daubert* hearing. Defendants nonetheless feel it is important to submit a short letter addressing what we believe is a misstatement in plaintiffs' post-hearing brief.

On page 16 of their brief, plaintiffs contend that a July 18 statement by the *New England Journal of Medicine* ("NEJM") regarding p values undermines defendants' and their experts' positions regarding statistical significance. This suggestion is false. The NEJM explicitly states that it ***will*** continue to require p levels for ***primary endpoints*** of a study (i.e., the main object of the study) for which a statistical analysis is prespecified. In this setting, the NEJM states, "the significance level from [the prespecified analysis] is a reliable indicator of the extent to which the observed data contradict a null hypothesis of no association" (i.e., statistical significance is meaningful in that context).[1] Given that ovarian cancer was a primary endpoint of the case-control studies on which plaintiffs and their experts rely, the NEJM's change in policy has no relevance to the literature at issue in this litigation. Moreover, while the NEJM will not require p levels for ***secondary endpoints***, its principal concern with statistical significance in the latter situation is ***false positives***, not false negatives,[2] making it all the more irrelevant to the *Daubert* issues before the Court.

Andrew B. Joseph
Partner responsible for Florham Park Office

[1] *See* Harrington, et. al, *New Guidelines for Statistical Reporting in the Journal*, 381 N.E.J.M. 285, 286 (July 18, 2019).

[2] *See id.* at 285 ("When 10 tests are conducted, the probability that at least one of the 10 will have a P value less than 0.05 may be as high as 40% when the null hypothesis of no difference is true"). In other words, there is as much as a 40% chance that an association that looks statistically significant is actually spurious even though the p value is nominally 0.05, which would typically be understood to mean that there is only a 5% chance that it is spurious.

In short, plaintiffs' suggestion that the NEJM statement demonstrates that defendants' positions are "erroneous" and Dr. Diette is "wrong" (Pls.' Br. at 16) grossly misinterprets the NEJM's statement.

Respectfully submitted,

Susan M. Sharko

cc: All Counsel of Record (Via ECF)